

Unclog the Innovation Bottleneck at our Nation's Universities

Monday, November 09, 2009

Blog BioTech

by Dr. Renee Kaswan

Choice and open competition in a free market – they're the pillars on which the U.S. economy rests. Yet the very thing they are designed to foster – innovation – is at risk, because the process by which innovations come to market at universities undermines open competition and inhibits inventor choice.

The federal government invests \$30 billion per year in medical research through the National Institutes of Health (NIH), and the stimulus added another \$10 billion over two years. The investment is designed to lead to innovations that can improve the nation's health, increase productivity and drive down costs.

But the Bayh-Dole Act of 1980, a law designed to cut through bureaucracy and get these inventions into the marketplace faster, has instead created another bottleneck that keeps that innovation in the lab and out of the hands of the taxpayers who paid for it.

Prior to the enactment of Bayh-Dole, the U.S. government had accumulated 28,000 patents, but only 5 percent had been commercially licensed because of the bureaucratic red-tape surrounding government-owned patents. The Act was designed to avoid government bureaucracy by permitting universities to retain title to innovations that resulted from publicly funded research performed by its faculty. The idea was that the people who created the innovation would have more incentive to make their ideas commercially viable and bring them to the marketplace. Good idea -- but that is not what is happening at many universities.

Bayh-Dole requires that the university act as coordinator for inventions made with federal funds by its personnel. The Act does not require the university own this intellectual property or that it act as the sole means of commercializing it. But most universities implement the Act by compelling faculty and other research inventors, including students, to disclose their inventions to the institution's Technology Transfer Office and requiring that they assign all patent applications to the university's exclusive ownership. The effect is to squeeze inventions of all sorts, from biotechnology and nanotechnology to software and composters, through the same office.

This process has simply replaced one bureaucratic bottleneck with another by making faculty inventors subject to the same – often overworked or under-funded – office. If the university's Technology Transfer Office is low on funds for the year and does not want to pay a patent application fee, or if its licensing officer just left for a different job, chances are the innovation created from taxpayer money will never be commercially licensed – depriving the public of the benefits of taxpayer funded inventions.

As an inventor myself, I know how hard it is to bring a product to market. The bureaucracy my university set up under Bayh-Dole did nothing to help. But because it was my invention, I was motivated, fighting for 20 years to patent, license, and gain FDA approval for my invention. I know without my pushing every step of the way, my product would not now be helping millions of people and animals successfully treat dry eye disease. Yet when my hard work finally resulted in FDA approval and millions of dollars for the university, I was sued and my rights to my own invention were challenged.

Sadly, my experience is not unique. Universities currently have a monopoly over the patenting and licensing of inventions by their faculty and students. As with any monopoly, lack of competition means that there is little incentive for universities to improve the quality and efficiency of their Technology Transfer Offices. What is needed now is for a rule change by the agency overseeing the Act that gives inventors a choice on how to best commercialize their innovation.

A recent Federal Circuit Court decision in the case of *Stanford University v. Roche Molecular Systems, Inc.* could shake up the status quo in a beneficial way. The court confirmed that universities do not automatically have the right to claim ownership of a faculty researcher's federally funded invention, saying "Bayh-Dole does not automatically void ab initio the inventors' rights in government-funded inventions."

Instead of being forced to rely on a university office that may be under-staffed or staffed with professionals with the wrong area of expertise, faculty researchers should be given the opportunity to choose the venue that is best aligned with the industries and investors most familiar with the possible applications of the invention, to manage the process of commercially licensing the technology. In many cases, this may be the university Technology Transfer Office. But when it isn't, faculty and graduate student inventors should be allowed to work the investment community directly. They should have opportunities to partner with companies that have immediate use for inventive work, or with research-directed foundations to coordinate the deployment of their work. As the leading experts in their own inventions, they should have the opportunity to choose among competing offers to bring these inventions to market.

Choice pushes university Technology Transfer Offices to compete, and competition develops the necessary expertise and programs that will enable researchers to obtain commercial licenses and realize their dream of seeing their inventions help solve problems or improve lives. More important, choice keeps inventors motivated to make the personal commitment to commercialization that the arduous process requires, and ensures that taxpayers will be able to enjoy the benefit of their research investment as quickly as possible.

Dr. Renee Kaswan is founder of the non-profit www.IPAdvocate.org, former research professor at the University of Georgia and inventor of the billion-dollar drug Restasis®.

About Genetic Engineering & Biotechnology News (GEN) has retained its position as the most widely read biotechnology publishing brand around the globe since its launch in 1981. What began as a print publication has now expanded to leverage online media including web-exclusive news and features, webinars, videos, podcasts, and newsletters. GEN's therapeutic and technology coverage includes the entire bioproduct life cycle from early-stage R&D, to applied research including omics, biomarkers, as well as diagnostics, and to bioprocessing and commercialization.

Mary Ann Liebert, Inc.

Genetic Engineering & Biotechnology News is published by Mary Ann Liebert, Inc., the leading publisher of authoritative peer-reviewed journals as well as books and directories in biotechnology, biomedical research, clinical medicine, surgery, and healthcare.
Publication Frequency

GEN print issues are published 21 times a year—twice monthly, and one issue each in July, August, and December.